March 20, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr
rm 1-23
Rockville MD 20857

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To Whom It May Concern:

This letter is intended to provide comment on the FDA's Review and Revision of Compliance Policy Guides and Regulatory Requirements as they pertain to medical device refurbishers, rebuilders, reconditioners, servicers, and remarketers.

Under this effort, the FDA is exploring whether it should expand its regulatory authority beyond medical equipment manufacturers, to include the entities listed above.

As my experience in this field has been limited to the servicing of medical devices, I will limit my comments to that subject specifically.

As a taxpayer and a professional who has been in the medical device service business for over five years, I am categorically against any effort to regulate servicers of medical devices (including in-house hospital-based servicers and third-party servicers). The reasons for my position are as follows:

Such regulation is unnecessary. Hospital-based and third-party service organizations have been servicing medical devices for decades. Clinical engineering (the support and management of medical equipment in the health care environment) has been recognized as a discipline since the mid-1960's. What problem are we trying to solve with FDA regulation? Are there reports of rampant inappropriate service being done to medical equipment? I do not know of even one independent study which links medical device failures to poor service by hospital-based service personnel or third-party service. To be sure, some service organizations are better than others. However, even with relatively poor service, it is difficult with today's medical devices to create a situation where the patient in danger. In any case, the medical equipment service industry has matured over the last 30 years to an extent that market forces weed out poor service organizations very quickly.

There is already a level of regulation of medical device servicing. The Joint Commission on the Accreditation of HealthCare Organizations (JCAHO) already closely scrutinizes medical equipment maintenance programs as part of its accreditation process. A rigorous review of medical equipment maintenance records, policy, and performance is already an integral part of any JCAHO inspection of a hospital. How will additional regulation add value to this process? The JCAHO has decades of experience in working with medical equipment management programs (including those run by third-party service organizations). It is hard

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to imagine government regulation and extra paperwork doing anything but duplicating JCAHO processes. (Note: the College of American Pathologists is another organization that regulates medical device service: specifically in hospital laboratories).

Such regulation would add to the cost of health care and would be a waste of government and health care provider resources (without an accompanying benefit to the patient). Drawing on the experiences of medical equipment manufacturers, requiring in-hospital and third-party servicers to comply with FDA current good manufacturing practice would add a tremendous paperwork burden to hospitals. In addition, the FDA would have to draw on its limited resources to administer this additional regulation. In my opinion, the FDA needs to concentrate its resources on improving on and expediting the approval of medical devices (as dictated by Congress), rather than wasting time and resources regulating an industry it knows little about. Additional regulation would provide no benefit to the patient (which is why an organization like FDA exists). How will a patient monitor be fixed sooner or better with CGMP regulation?

Such regulation could actually endanger patient care. Hospital financial resources are already being pressured by changes in reimbursement and changes in the health care market. The cost of CGMP regulation of even third-party medical equipment servicers would be passed on to health care providers who can ill afford such waste. Forcing hospitals to spend precious time and resources on government-mandated paperwork reduces resources available for the patient. Time spent filling out CGMP paperwork could be spent training nurses on using a new medical device, or fixing a broken x-ray machine.

I hope that this letter clearly communicates my strong opposition to any regulation of medical equipment servicers. If you have any questions or need additional information, please contact me at (704) 676-4856.

Sincerely,

Brian Porras, MSBME

cc: Senator Lauch Faircloth
Senator Jesse Helms

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